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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,169	11/12/2002	Shaomeng Wang	P 0280714	9701

909 7590 01/13/2004

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EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,169	WANG ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply specified above is less than thirty (30) days, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *17 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *10-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-9 in Paper No. 4, dated Oct. 17, 2003 is acknowledged. The traversal is on the ground(s) that no good reason was given by the examiner. This is not found persuasive because the examiner provided no substantive reason why the claims should be restricted and applicants request provision of a substantive reason.

It is noted in the record wherein a restriction was requested that the basis of restriction was made based on lacking of general inventive concept under PCT Rule 13.1 and PCT rule 13.2 with its detailed guidelines under PCT Administrative Instruction Annex B, section (f) under Markus practice, subscript (B)v. Based on the rules as recited supra, the examiner *provided* evidence that "at least one Markush alternative is not novel" with prior art citing CA 74:68906. Therefore, not only the basis or restriction was recited with citation of rules, a substantive provision of *evidence* was also made to fulfill all the requirement as recited by the rules.

Further the section of MPEP describing lack of unity in national stage is cited herein:

37 CFR 1.475. Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Please note that on pages 1-2 of the specification it was clearly delineated that controlling dopamine flow, modulating dopamine reuptake, treating neurological disorder and treating cocaine abuse are distinct method involving independent and distinct process. On page 14, it was explicitly stated that "Although both cocaine and dopamine bind to the DAT, recent

mutagenesis and pharmacokinetic studies provide evidence that dopamine and cocaine *do not share* and identical binding site on the DAT". In addition, the section of detailed description provided extensive testing method on different activity must be tested in picking among the individual compounds under the Markush claim for one activity or the other, i.e. some individual compounds have cocaine antagonist activity, others have dopamine receptor inhibition, some have dopamine reuptake inhibition etc. Further, claims 23-24 do not share the same scope with the rest of the claims even on compounds. Therefore, in view of the substantive evidence that at least one of the Markush compound is not novel and each individual or subgroup of Markush compounds were identified for suitability in controlling dopamine flow, modulating dopamine reuptake, treating neurological disorder and treating cocaine abuse, it was found that Groups I-V lack the "*special technical features*" under the guidelines of 37 CFR 1.475.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-9 are examined. Claims 10-24 are withdrawn from consideration per 37 CFR 1.142(b).

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The chemical structure as claimed on page 64, last paragraph of claim 1 wherein "R3 is a covalent bound replacing the hydrogen in a hydroxyl group of R1 when R1 is alcohol or hydroxyl" is very confusing. It is unclear what is the structure and what constitute the linkage between the R3 attached carbon and the oxygen attached to R2.

In view of the ambiguity, the claim is also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Please note that the claim requires that R3 is a "covalent bond" therefore must be the structure of

No description or enabling support can be found in the specification as to how to make or use a compound of the above chemical structure.

3. The scope of claim 1 compounds wherein R2 or R4 is alkyl,..... etc. encompassed an enormous anticipatory and/or obviousness compounds which has been searched and a copy of the search result with compounds clearly delineated is attached. In view of such enormous prior art, individual discussion of each compound will not be made but will be limited to the scope of claim 1 wherein R2 is (optionally substituted)phenylcarbonyl , R4 is (optionally substituted) phenyl, and R3 is F, Cl, Br, I, OH, OR''''' or OC=OR''''' will be detailedly discussed in the following sections.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102 (a) or (b) as being anticipated by :

US 2,489,669, see col.1 and 6 lines 35-75, examples 5-6;
US 3,408,445, see col. 2 line 65-col. 3 line 30, example 1;
US 3,965,104, see col. 4-8, examples 1-10;
US 3,887,568, see col. 1 line 45 and examples 1-3;
US 3,591,593, see col. 2 formula I, examples 1-23
Draper, CA 74:68906, RN 31088-27-4;
Casy et al. CA 130 :351978, See RN 224948-86-1, 224948-87-2, 224948-90-7
Gardner et al. CA 52 :34599, see 1455-17-7, 101729-59-3, 5409-66-5 ;
Geigy et al. CA 63:3273, see RN 1563-22-0, 1599-87-7.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1-9 are rejected under 35 U.S.C. 102 (f) as being anticipated by the following references having a different inventorship:

CA 133:66179, RN 224948-86-1, .

CA133:171745, RN 224948-87-2, 224948-90-7,
CA 133:339052, see RN attached,

The above references although published after the priority filing, indicated "another" was in possession of the claimed compounds for the same or different utility. The issue of who is the "first" to invent must be resolved.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Steiner et al. US 5,512,584.

See compounds of examples 1-39 (col. 4-8) for treating anxiety (see col. 16, claim 8).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steiner et al. '584 in view of Casy Ca 130,Yanai et al. CA 129 and Foy CA 118.

Determination of the scope and content of the prior art (MPEP §2141.01)

Steiner et al. '584 disclosed anticipatory compounds for the claimed method of claim 3 as delineated supra which is incorporated by reference.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Steiner et al. '584 disclosed all the elements of the claims **except** the exemplified species for treating anxiety was unsubstituted phenyls or fluoro- or bromo-subsituted phenyls (see col. 4 example 1, lines 15-60). Generically, Steiner et al. '584 taught that fluorine and chlorine substitution are optional choice (see col. 1 line 51). In analogous art, such compounds with alkyl substitution were taught to be analogous structure for it biological function (see Casy CA 130).

Finding of prima facie obviousness---rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. Yanai et al. taught that treating anxiety involved histamine receptor function. Foy taught that cocaine function involves histamine receptor function. Casy taught that structural configuration of unsubstituted phenyl or methyl- or chloro-substituted phenyl embraced by the Steiner '584 or the instant claims are "analogous" in biological functionality on the receptors. Therefore, one in possession of the above references is in possession of the instant claims since the unsubstituted or fluorine substituted species were disclosed by Steiner '584 to be useful in treating anxiety, other analogous compounds having structure for similar biological function would be expected to perform similarly (Casy) and such performance is known to be tantamount as "cocaine function" (Yanai or Foy).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Celia Chang
Primary Examiner
Art Unit 1625

OACS/Chang
Jan. 7, 2004